Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

VOLUME XXV • ISSUE I JANUARY/FEBRUARY 2025

ELABORATIONS is a free bi-monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and the Medical Test Site (MTS) Program.

Secretary, DOH: Jessica Todorovich (Interim Secretary of Health)
Acting Health Officer: Scott Lindquist, MD
Director, PHL: Vince Aoki, PhD (Acting Laboratory Director)
Program Manager, MTS: Jessica Holloway
Survey & Investigation Manager, MTS: Lori Eschenbacher
Editor & Circulation: Chuck Talburt

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:
ELABORATIONS
1610 NE 150th St
Shoreline, WA 98155
e-mail address: chuck.talburt@doh.wa.gov
NOTE: Letters to the editor may be published unless specified otherwise by the author.

Website access:
Department of Health
Medical Test Site Program
Public Health Laboratories

Inside This Issue

Washington State Medical Test Site Program

The top 10 deficiencies identified in 2024

The Washington State Department of Health Medical Test Site (MTS) survey team inspects laboratories under the Medical Test Site (MTS) licensing program. This article outlines the top 10 deficiencies cited during these inspections and includes compliance tips. The MTS Washington Administrative Code (WAC) citation appears after each item.

#1: WAC 246-338-060(1)(c)

(1) Medical test site owners must: (c) Meet the standards for personnel qualifications and responsibilities in compliance with federal regulation, as listed in 42 C.F.R. Part 493 Subpart M - Personnel for Non-waived Testing.

This deficiency is typically cited when the laboratory:

- does not have anyone meeting the qualifications or fulfilling the duties of a technical consultant (for moderate complexity testing) or a technical supervisor (for high complexity testing),
- the assigned technical consultant or technical supervisor does not qualify,
- there is no evidence of the duties the director delegated to the technical consultant or technical supervisor, or
- There is no evidence that the responsibilities of the technical consultant or technical supervisor are met.

Subpart M Requirements:

§ 493.1411 Standard; Technical consultant qualifications

§ 493.1413 Standard; Technical consultant responsibilities

§ 493.1449 Standard; Technical supervisor qualifications

§ 493.1451 Standard: Technical supervisor responsibilities

§ 493.1445 Standard; Laboratory director responsibilities

See the Laboratory Director Responsibilities brochure for more information

Compliance Tips:

- Review the duties the laboratory director may delegate to the technical consultant and technical supervisor.
- Review the responsibilities for the technical consultant and technical supervisor.
- Assign the delegated duties in writing.
- Ensure the duties are being met and have been assessed by the laboratory director annually.

#2: WAC 246-338-090(2)(c)

(2) The medical test site must establish written criteria for and maintain appropriate documentation of (c) Equipment function checks.

Compliance Tips:

- Review all manufacturer product inserts and regulations to identify function checks required by the manufacturer or regulating organizations. Establish a schedule to perform these function checks and document that they have been performed.
- Review schedule for function checks when new tests, methods, or equipment are installed and put into use. Follow manufacturer product inserts and regulatory requirements.
- Rotate these function checks among all testing personnel who are responsible for instrument performance.
- Review documentation to validate that equipment functions checks are being performed as required.

#3: WAC 246-338-060(3)(b)(iv)

(3) Medical test site directors must: (b) Evaluate, verify, and document the following related to technical personnel: (iv) Maintenance of competency to perform test procedures and report test results;

This deficiency is typically cited when the laboratory does not have documentation of competency assessments for staff or does not include all six elements of competency assessment listed below. The medical test site must evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and

proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

- Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
- Monitoring the recording and reporting of test results;
- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
- Direct observations of performance of instrument maintenance and function checks;
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
- Assessment of problem-solving skills.

Compliance Tips:

- Have a written policy defining personnel competency testing for your facility.
- Ensure the assessment includes the six required elements of competency assessment
- Sign and date the document.
- Document the initial training of new testing personnel, assess competency at about six months and annually thereafter.
- Ensure staff have documentation of training in new methodologies.
- Document remedial action for personnel failing the competency assessment.

#4: WAC 246-338-080(1)(a)

(1) The medical test site must establish and implement a written quality assurance plan, including policies and procedures, designed to: (a) Monitor, evaluate, and review quality control data, proficiency testing results, and test results, including biannual verification.

Compliance Tips:

- Each medical test site performing moderate complexity (including PPMP) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program. The quality assurance program must be designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic).
- The medical test site's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable, and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the medical test site must revise policies and procedures based upon the results of those evaluations. The medical test site must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.
- The quality assurance plan must be approved, signed and dated by the laboratory director.

#5: WAC 246-338-080(3)

(3) The medical test site must establish criteria for and maintain appropriate documentation of any remedial action taken in response to quality control, quality assurance, personnel, proficiency testing, and transfusion reaction investigations.

This deficiency is cited when there is no documentation of corrective action taken for the problems listed above. It is also cited when the laboratory fails to recognize that it has a failure and/or does not take ***effective*** action to correct the problem.

Compliance Tips:

- Establish an effective mechanism to recognize that problems exist, and document appropriate corrective action.
- Review documentation regularly and record the review.
- Discuss compliance issues with staff and leadership when necessary.
- Document, document, and document.

#6: WAC 246-338-050(1)(a)

(1) All licensed medical test sites, excluding those granted a certificate of waiver, must: (a) Comply with federal proficiency testing requirements listed in 42 C.F.R. Part 493 - Laboratory Requirements, Subparts H and I.

Participation in proficiency testing (PT) is required for all regulated analytes tested in your laboratory. The MTS website has information about PT requirements and a list of the regulated analytes under the "Proficiency Testing" section on the left side of the screen. For non-regulated analytes, the laboratory can enroll in PT or use an alternative method (biannual verification) to comply with the regulation. PT is not required for waived tests but is recommended as good laboratory practice.

Compliance Tips:

- Enroll in PT for all regulated analytes each year.
- Enroll in PT or develop a biannual verification (BV) policy for non-regulated analytes; test at least two samples per analyte twice per year.
- Check the attestation statements for signatures of the laboratory director (or designee per delegation policy) and the testing personnel.
- Rotate PT sample testing among all testing personnel.
- Ensure the PT samples are treated in the same manner as patient samples.
- Document the review of PT or BV results and any remedial action to correct problems including those results that are not graded by the PT company.

#7: WAC 246-338-060(3)(b)(i)

(3) Medical test site directors must: (b) Evaluate, verify, and document the following related to technical personnel: (i) Education, experience, and training in test performance and reporting test results.

The MTS director must evaluate, verify, and document the education, experience, and training for all testing personnel. This deficiency will be cited if there is no documentation showing that the testing

personnel are qualified to perform laboratory testing, or if there is no documentation of initial training for new testing personnel.

Compliance Tips:

- Establish a hiring protocol that includes documentation that testing personnel are qualified to perform moderate or high-complexity testing by having on-site copies of diplomas or transcripts with the date of graduation.
- Verify that current personnel have documentation on record that they are qualified to perform laboratory testing.
- Establish a protocol to have any qualification documentation that is in a foreign language translated into English so the surveyor will be able to read the qualifications.
- Foreign transcripts must be reviewed by an approved transcript evaluation agency to determine U.S. degree equivalency.
- Perform and document training before the employee performs patient testing unsupervised. This training should include the following at minimum:
    - The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens.
    - The skills required for implementing all standard laboratory procedures.
    - The skills required for performing each test method and for proper instrument use.
    - The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed.
    - A working knowledge of reagent stability and storage.
    - The skills required to implement the quality control policies and procedures of the laboratory
    - An awareness of the factors that influence test results; and
    - The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

#8: WAC 246-338-060(3)(a)(i)

(3) Medical test site directors must: (a) Establish and approve policies for: (i) Performing, recording, and reporting of tests.

Compliance tips:

- Ensure that new procedures are reviewed and approved by the laboratory director.
- Ensure that new laboratory directors review and approve the policies and procedures promptly.
- Review eCFR :: 42 CFR 493.1445 -- Standard; Laboratory director responsibilities. and eCFR :: 42 CFR 493.1407 -- Standard; Laboratory director responsibilities.
- See Laboratory Director Responsibilities brochure for more information.

#9: WAC 246-338-090(3)(a)(i)

(3) The medical test site must maintain documentation of: (a) Expiration date, lot numbers, and other pertinent information for: (i) Reagents;

Compliance tips:

- Review expiration dates for materials in the laboratory.
- Review "new" expiration dates after aliquoting as required by the test's product insert or reagent box.
- Ensure secondary containers contain the identity, lot number and expiration date of the contents.
- Ensure supplies are stored in the appropriate temperature and humidity as specified by the manufacturer, and if moved from a freezer to a refrigerator, document the change of the expiration date if applicable.

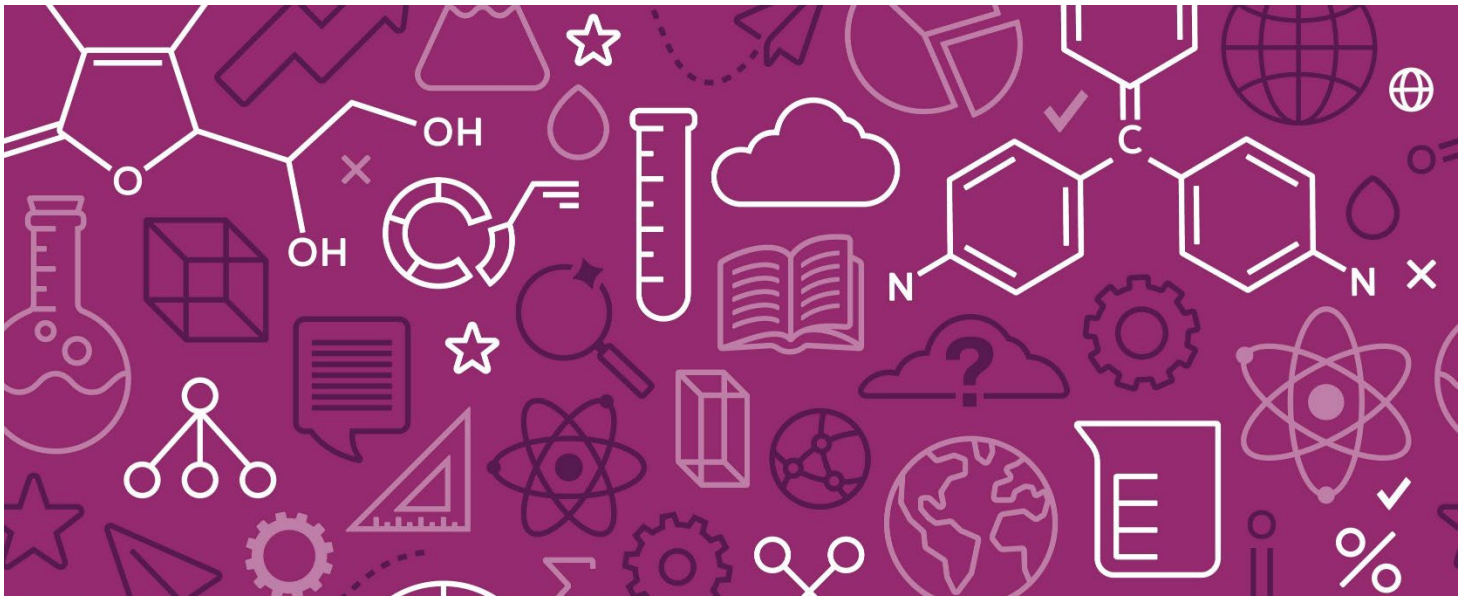
#10: WAC 246-338-090(2)(a)

(2) The medical test site must establish written criteria for and maintain appropriate documentation of:
(a) Temperature-controlled spaces and equipment;

Include the monitoring of room temperature for reagents stored at room temperature or if the manufacturer specifies a specific temperature range and percent humidity when specified by the test method or equipment. Temperature storage and ranges are found in the package insert and/or on the reagent box.

Compliance Tips:

- Establish acceptable temperature ranges. If the manufacturer recommends different ranges, the range used should be the most restrictive.
- Record temperatures on each day of business, including room temperature if specified for reagents, supplies, or equipment.
- Document corrective action taken when temperatures are outside acceptable limits.
- Re-record temperatures several hours after an adjustment to the thermostat.
- Ensure that the thermometers are calibrated and accurate.



Practice Guidelines

The following practice guidelines have been developed by the Washington Clinical Laboratory Advisory Council. They can be accessed at the Medical Test Site Program website.

- Acute Diarrhea
- Anemia
- ANA
- Bioterrorism Event Management
- Bleeding Disorders
- Chlamydia
- Diabetes
- Group A Strep Pharyngitis
- Group B Streptococcus
- Hepatitis
- HIV
- Infectious Diarrhea
- Intestinal Parasites
- Lipid Screening
- PAP Smear Referral
- Point-of-Care Testing
- PSA
- Rash Illness
- Red Cell Transfusion
- Renal Disease
- STD
- Thyroid
- Tuberculosis
- Urinalysis
- Wellness

2025 Virtual Joint Spring Seminar (ASCLS-WA, ASCLS-OR, & ASCLS-AK), April 3-4

2025 Virtual Northwest Laboratory Symposium (NWMLS), October 2-3

The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to chuck.talburt@doh.wa.gov. Information must be received at least one month prior to the scheduled event. The editor reserves the right to make final decisions on inclusion in *ELABORATIONS*.

ELABORATIONS
Washington State Department of Health, 1610 NE 150th St, Shoreline, WA 98155

Washington State Department of HEALTH

DOH 505-068 January 2025 (CS)
To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.